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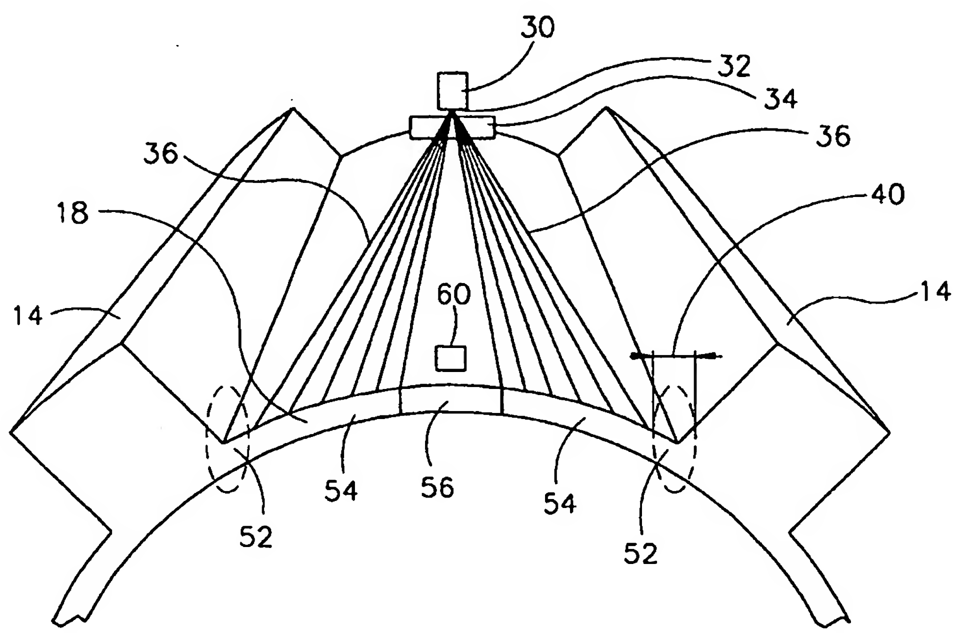

(57) Abstract

A method of metal processing an orthopedic implant. The method includes providing an orthopedic device having at least one expandable portion and at least one non-expandable portion, and selectively annealing at least part of said expandable portion. Preferably the non-expandable portion is not significantly annealed. Preferably, the implant is an intramedullary nail.

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METAL PROCESSING METHOD

RELATED APPLICATIONS

This application is a continuation-in-part of PCT application PCT/IB98/00523, which designates the U.S., and of US application serial number 09/036,719 filed March 6, 1998, the disclosures of which are incorporated herein by reference. This application also claims the benefit under 119(e) of US provisional application number 60/012,184, filed February 16, 1999, the disclosure of which is incorporated herein by reference. This application is also related to two PCT applications, which designate the US, are filed on even date in the Israel receiving office, by applicant Disc-o-tech Medical technologies Ltd. and have attorney dockets 110/01325 and 110/01357, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to metal processing methods. More specifically, the invention relates to metal processing methods designed to give the same piece of metal different properties in different sections.

Description of the Related Art

It is known that subjecting metal to certain machining processes changes the mechanical properties of the metal. For example, if steel wire or tubing is cold worked, its tensile strength and yield strength are improved, however its elongation ratio remains relatively low. In contrast, if steel wire or tubing is annealed, its tensile and yield strength remains low, however its elongation ratio becomes relatively high. It is sometimes difficult to select the right machining process to provide desirable mechanical properties in a given piece of metal since one process will usually result in a piece of metal having at least one relatively poor mechanical property.

One example of a device for which it is difficult to select a machining process is an intramedullary bone fixation nail as described in co-pending U.S. Patent Application No. 09/036,719 filed March 6, 1998 and assigned to the same assignee as the present invention, the teachings of which are incorporated by reference herein. As shown in Figs. 1A-B, the intramedullary nail 10 is insertable into the central cavity in a long bone 5 and is used to maintain pieces of broken long bones in a relative fixed position so that healing is facilitated. The nail 10 is inserted in a collapsed configuration through the marrow (not shown) as shown in Fig. 1A. Thereafter, the nail 10 is expanded by use of saline, for example, to the expanded configuration shown in Fig. 1B; the marrow is compressed but not harmed. The nail 10 is

preferably made from a single piece of stainless steel and includes longitudinal support ribs 14 and flexible connecting webs 18. Ribs 14 support the bone until it heals.

The collapsed configuration of Fig. 1A shows the webs 18 in a bent, cloverleaf arrangement. After the nail is expanded, the longitudinal ribs 14 contact and support bone 5, while webs 18 form a relatively cylindrical shape. Because webs 18 must be able to flex from the collapsed configuration of Fig. 1A to the expanded configuration of Fig. 1B, webs 18 must be very thin and flexible. However, the longitudinal ribs 14 are designed to provide support for a healing broken bone and thus are generally made durable and relatively strong. Yet it is preferred to manufacture the nail 10 from a single piece of stainless steel tubing. Simply cold working the entire nail is not a recommended option; the ribs 14 would be sufficiently strong, however the thin webs 18 would not be sufficiently flexible and would crack when expansion of the nail was attempted or when the nail is folded into its collapsed configuration. Annealing the entire nail is also not a recommended option; the webs 18 would be sufficiently flexible, however the ribs 14 may not be sufficiently strong and the effectiveness of the nail to support a broken bone would be compromised.

SUMMARY OF THE INVENTION

An aspect of some preferred embodiments of the invention relates to selectively processing metal, especially a medical implant, so that different parts of the metal have different mechanical characteristics and especially different yield strengths and/or different elongation ratios. In a preferred embodiment of the invention, portions of the implant that are designed to be expanded are annealed, so that they have better elongation properties. In a preferred embodiment of the invention, the selective processing is applied to implants that are hardened by cold-working during manufacture.

In a preferred embodiment of the invention, the selective processing method is selective annealing, preferably applied using e-beam heating of the implant at or near the parts to be annealed.

An aspect of some preferred embodiments of the invention relates to methods of manufacturing a medical implant, especially an orthopedic implant such as an intramedullary nail, so that the implant has desirable properties. In a preferred embodiment of the invention, the implant is formed of a single piece of metal. Alternatively, the implant is formed of two or more pieces of metal that are joined together and have undesirable mechanical characteristics after they are joined due to the joining process and/or the separate manufacture methods of the pieces.

An aspect of some preferred embodiments of the invention relates to a screw for engaging a bone, which has an expandable head and at least one protrusion thereon. In a preferred embodiment of the invention, the head and/or the protrusions are selectively at least partially annealed or hardened. In an exemplary embodiment, the entire head including the protrusions is annealed and then only the protrusions are hardened. Alternatively or additionally, the entire head including the protrusions is cold-worked to harden it and then the head and/or the outside of the protrusions are annealed to allow their expansion. The protrusions may be formed of one piece with the head or they may be attached onto the head, for example by welding.

In a preferred embodiment of the invention, a metal piece is processed by first cold working the piece via a conventional process such as cold rolling. The cold worked piece is then annealed in predetermined sections. Preferably, but not necessarily, a boundary area between annealed and non-annealed (but previously cold worked) sections is maintained to prevent weakening of the portion of the piece where the sections meet.

In a preferred embodiment, a method for manufacturing intramedullary bone fixation nails is provided. A piece of steel tubing is cold rolled. The tubing is then machined to provide one or more longitudinal ribs interconnected by thin membranes or webs. The webbed portions are then annealed. The longitudinal ribs thus have the properties of cold worked steel, i.e., strength and durability, while the webbed portions are imbued with increased flexibility. Preferably, the annealing is performed by an electron beam gun.

There is therefore provided in accordance with a preferred embodiment of the present invention, a method of metal processing of an orthopedic implant, including providing an orthopedic device having at least one expandable portion and at least one non-expandable portion, and selectively annealing at least part of the expandable portion, using an energy beam.

Preferably, the method includes not significantly annealing the non-expandable portion. Preferably, the non-expandable portion is elongated by the expandable portion. Preferably, the method includes significantly annealing at least a part of the non-expandable portion. Preferably, the method includes selectively annealing only part of the expandable portion. Preferably, the selective annealing maintains a boundary, non-annealed area between the expandable portion and the non-expandable portion.

Preferably, the method includes cold-working the implant prior to the selective annealing. Preferably, the expandable and non-expandable portions include elongate sections

of the implant. Preferably, the implant includes an intramedullary nail, an orthopedic implant, a dental implant, a hip screw or a hip implant, e.g., a mesh-type implant.

Preferably, the non-expandable portion includes a thick portion of the implant and the expandable portion includes a thin portion of the implant.

Preferably, the beam includes an electron beam, a laser beam and/or a plasma beam.

Preferably, the selective annealing includes annealing both by directly heating a part of the implant and by indirectly heating a second part of the implant using heat transported from the directly heated part of the implant.

Preferably, selective annealing includes protecting at least a portion of the implant from annealing heat. Preferably, the protecting includes providing a heat sink adjacent non-annealed portions and/or actively cooling non-annealed portions.

Preferably, the method includes monitoring a temperature of at least a part of the implant using a sensor. Preferably, the monitored part includes an annealed part. Alternatively or additionally, the monitored part includes a part not to be annealed.

Preferably, monitoring the temperature includes monitoring the temperature such that the annealed parts do not melt. Alternatively or additionally, monitoring the temperature includes monitoring the temperature to be above a level sufficient for annealing. Preferably, selectively annealing includes controlling an intensity of heating, responsive to the sensor output.

Preferably, the controlling includes closed loop controlling and/or open loop controlling. Alternatively or additionally, the controlling includes modifying a characteristic of the energy beam in real-time. Preferably, the controlling includes modifying a characteristic of the energy beam in a later run, responsive to measurements in a previous annealing run. Preferably, the selective annealing includes repeating heating a same location several times, until a desired annealing effect is achieved.

Preferably, the annealing includes annealing an entire thickness of the expandable portion. Preferably, the annealing increases the elongation of the annealed parts to at least 30%, 40%, 50% or 60%. Preferably, the annealing increases the elongation of the annealed parts from about 12%.

There is further provided in accordance with a preferred embodiment of the present invention, an intramedullary nail, including a plurality of elongate cold-worked portions, and a plurality of elongate annealed portions.

Preferably, the cold-worked portions are separated from the annealed portions by a at

least one boundary portion. Preferably, the boundary portion includes an expandable portion of the nail. Preferably, the cold-worked portions are thick and non-expandable. Preferably, the annealed portions are thin and expandable. Further preferably, the annealed portions are annealed to their entire thickness. Preferably, the nail is formed of stainless steel and/or titanium.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and combinations of features for which protection are sought are pointed out with particularity in the appended claims. The invention, both as to its general principles and implementation together with it objects and advantages may be more fully understood by reference to the following non-limiting description of preferred embodiments thereof, taken in conjunction with the accompanying drawings:

Fig. 1A is an in situ cross-section of an intramedullary bone fixation nail, in a collapsed state, manufacturable in accordance with a preferred embodiment of the present invention;

Fig. 1B is an in situ cross-section of the intramedullary bone fixation nail of Fig. 1A in an expanded state;

Fig. 2 is a cross-section of a metal tube;

Fig. 3 is a cross-section of the metal tube of Fig. 2 after it has been machined in accordance with a preferred embodiment of the present invention;

Fig. 4 is a front perspective and schematic view of a selective annealing step in accordance with a preferred embodiment of the present invention;

Fig. 5 is a schematic block diagram of a feedback control system employed in accordance with a preferred embodiment of the present invention;

Figs. 6A and 6B illustrate a dental implant in accordance with a preferred embodiment of the invention; and

Figs. 7A and 7B illustrate hip screws, in accordance with preferred embodiments of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Spatially selective annealing, as well as other treatments for medical implants contemplated by some embodiments of the present invention, can be applied to a range of medical implant types. As an exemplary first implant, the manufacture of an intramedullary nail will be described. All the details that can be applied to the manufacture of intramedullary nails may also be applied to other types of medical implants, especially as described below.

Fig. 2 and Fig. 3 illustrate a method of manufacturing an intramedullary nail, in accordance with a preferred embodiment of the invention. First, a steel tube 20 is provided as shown in Fig. 2. The entirety of tube 20 is preferably cold worked in one manner or another, for example, cold rolling. Next, as shown in Fig. 3, outer portions 22 (in outline) of the cold rolled steel tube 20 are removed by machining. Thus, what remains from tube 20 is substantially nail 10 formed of thin membranes or webs 18 between thicker longitudinal ribs 14. It is noted that nail 10 as shown in Fig. 3 may be produced using additional or alternative methods than machining, such as welding of ribs 14 to a thin tube.

Generally, as a result of the processing of tube 20 and/or the alternative production methods, the metallurgical properties of webs 18 and/or ribs 14 are not optimum. In the production method described this far, webs 18 do not elongate well, which may cause cracking of the webs when nail 10 is folded (as in Fig. 1A) or expanded (as in Fig. 1B).

Fig. 4 illustrates a preferred embodiment of the inventive selective annealing process. An electron gun 30 is preferably provided to heat a to-be-annealed web 18. Gun 30 preferably produces a beam 32 which is selectively directed to areas of web 18. The beam preferably raises the surface temperature of web 18 to an annealing temperature. For example, if tube 20 comprises 316L grade 2 steel per ASTM F138-92, web 18 is preferably heated to approximately 1000°C. A sensor 60 is preferably placed near the surface of web 18 being annealed to measure the temperature of web 18. The measurements of sensor 60 are preferably used to ensure that web 18 is not overheated (particularly that web 18 is not melted) and/or to verify that the web is heated sufficiently for annealing, as described hereinbelow. Sensor 60 is preferably used to monitor the temperature at portions directly hit by beam 32. Alternatively or additionally, sensor 60 monitors the temperature of portions not directly hit by beam 32 but which are heated and annealed because they are adjacent to portions hit by the beam. Further alternatively or additionally, sensor 60 monitors the temperature of areas of webs 18 and/or ribs 14 which are not to be annealed, preventing these areas from being annealed. Preferably, sensor 60 measures the temperature of the monitored portions before and/or after they are heated. Alternatively or additionally, sensor 60 measures the temperature of the monitored portions while they are being heated.

In a preferred embodiment of the present invention, a beam splitter 34 is placed in the path of beam 32 in order to split beam 32 into two (or more) sub-beams 36. Preferably, sub-beams 36 cover most, but not all, of web 18. Preferably, sub-beams 36 hit two zones 54 which are directly heated by the excitation caused by the electrons in the electron sub-beams 36.

Preferably, a central zone 56, between zones 54, not directly hit by beam 32, is indirectly annealed due to the heat generated in zones 54. Alternatively to using beam splitter 34, beam 32 directly hits zones 54.

In some preferred embodiments of the present invention, certain areas of web 18 and/or of ribs 14 which are not to be annealed are kept cool by providing a heat-sink or active cooling adjacent these areas. In a preferred embodiment of the present invention, ribs 14 (and/or parts of web 18) are cooled using an attached heat sink or by providing a cooling fluid inside tube 20, under ribs 14. Alternatively, parts of nail 10 are coated with an ablatable material, preferably using a suitable mask. When the beam hits the ablatable material the ablatable material protects the part of nail 10 beneath it from the beam and/or evaporates and cools the surface beneath it by its ablation.

It is noted that the beam splitting and/or cooling methods may be used to anneal substantially any useful pattern on webs 18, and generally on medical implants.

Sub-beams 36 are optionally, but not necessarily, positioned so as to leave a boundary region 52 between web 18 and an adjacent longitudinal rib 14. Boundary region 52 is shown for a single position of sub-beams 36 and preferably runs all along the boundary between rib 14 and web 18. In boundary region 52, beam 32 does not substantially anneal web 18. Preferably, ribs 14 serve as a heat sink, so that region 52 is not significantly annealed. The defining of boundary regions 52 prevents the weakening of tube 20 at the borders between longitudinal ribs 14 and webs 18. If boundary regions 52 were annealed, regions 52 could be significantly weakened, and nail 10 might crack along region 52. Also, by maintaining regions 52 un-annealed, a larger radius of curvature is achieved at regions 52. In a preferred embodiment of the invention, a tool used for folding nail 10 includes a rounded element placed against region 52, for preventing too sharp a fold at the region. The size and shape of region 52 may be dependent on several parameters, possibly including one or more of: the implant type, implant geometry, heating feedback method, heat source, implant material and prior working. Suitable patterns for boundary regions 52 are also described in German Gebrauchsmuster DE 299 04 852 U1, the disclosure of which is incorporated herein by reference.

Sub-beams 36 or beam 32 preferably sweep the selected zones 54 with a constant pulse intensity and a constant velocity. In a preferred embodiment of the invention, sub-beams 36 repeatedly sweep over web 18 until a sufficient heating level is achieved. Alternatively to using a constant sweep velocity, the velocity is varied, for example slowed (or accelerated), to achieve a greater (or lower) local heating, for example for non-uniform parts of the implant or

near heat sinks. Alternatively or additionally, the pulse intensity or beam pattern are varied to achieve required heating levels. In preferred embodiments using a pulsed beam, the pulsing frequency, pulse form and/or ration between on and off periods is varied to achieve suitable heating patterns.

In an exemplary embodiment, a feedback control loop between electron gun 30 (or other heat source) and sensor 60, is provided, for example as shown in Fig. 5 which is a schematic block diagram of a feedback control system employed in accordance with a preferred embodiment of the present invention. Electron gun 30 heats web 18, and sensor 60 measures the temperature of web 18, for example using contact or non-contact pyrometery. For annealing, it is generally desired that web 18 be heated but not melted. Accordingly, sensor 60 is preferably linked to electron gun 30 via control line 70 and controller 72. When the temperature sensed by sensor 60 reaches a certain predetermined threshold set by controller 72, a signal is sent to electron gun 30 by controller 72 to reduce (or switch off) its beam intensity. Similarly, if the temperature sensed by sensor 60 is too low, a signal is sent to electron gun 30 by controller 72 to increase its beam intensity. Similar control mechanisms may also be used for velocity and pulsing parameters.

Alternatively or additionally, to using a sensor and a feedback loop, the heating may also be based on estimation and/or a calibration run, where exact temperatures are measured. Alternatively or additionally, an open-loop control system is used, wherein a sweep is repeated if sufficient temperatures are not achieved. Alternatively or additionally, to measuring temperatures, other sensors 60 may be used, for example an emissivity sensor, which can be used to detect changes in metallurgical properties of the heated metal. In a preferred embodiment of the invention, a combined temperature-and-emissivity sensor is used instead of sensor 60.

In some preferred embodiments of the present invention, a plurality of sensors 60 are used to monitor the annealing. For example, one or more sensors monitor the annealed area while others monitor the temperatures in areas which are not to be annealed. In a preferred embodiment of the invention, the temperature in one or more surface or depth points of web 18 not directly monitored by a sensor is estimated based on the readings of one or more of the other sensors.

In the context of the manufacture of an intramedullary bone fixation nail 10, annealing is preferably performed to increase the elongation ratio of web 18. For example, in an exemplary application, longitudinal ribs 14 generally have a relatively low elongation ratio of

between 5% and 20%, more typically between 10% and 15%. The low elongation ratio is generally because they were cold-worked. Annealed webs 18, on the other hand, preferably have an elongation ratio of at least 30% and preferably, 40%, 50% or even more, such as 60%, due to the annealing described above. A possible resulting low yield strength of webs 18 is less important in nail 10, as ribs 14 are meant to carry any body strain incident on the nail.

Alternatively or additionally to using electron gun 30, the source of heat used in annealing may be any other suitable beam source, such as a plasma gun or a laser. Further alternatively or additionally, contact sources are used. It is noted, however, that although electron beam apparatus is generally more expensive than laser beam apparatus and that electron beam apparatus requires a sterile environment, electron beams are preferable for selective ablation of medical implants due to the ease in controlling their energy output and beam pattern.

Alternatively or additionally to performing selective annealing, other spatially selective volume and surface treatments may be applied to medical implants. It is noted that medical implants are usually constructed from a small class of bio-compatible materials and, unlike, for example an automotive application, it may not be possible to select an alloy with all of a plurality of required properties. Thus spatially selective treatment is important. Exemplary metallurgical treatments which may be used in accordance with preferred embodiments of the present invention in spatially selective treatments are described, for example, in chapter 6, titled "Laser Surface Treatment", of "Laser Material Processing", 2nd edition, by William M. Steen, 1998, Springer publishers, the disclosure of which is incorporated herein by reference. Preferably, these metallurgical treatments may be applied as surface or volume treatments. Exemplary treatments applied to selective portions of medical implants include hardening, tempering, stress release and shock hardening. Although volume processing is preferred, in some implants, surface processing will be desired.

The selective treatment methods of preferred embodiments of the invention, may be employed on a large range of metals including, for example, stainless steel, titanium, super alloys and nitinol.

Although the above description has focused on intramedullary nails, other types of implants can be advantageously processed using selective treatment techniques.

Spinal fusion cages, and especially expandable cages, such as described in the above referenced PCT application filed on even date, may be annealed at points where they contact the bone, to assist in spreading of the cages under pressure. Alternatively or additionally, the

cages may be annealed at points where they bend.

In general, annealing is useful for parts which are to be deformed and/or significantly bent, for example, in expanding devices, such as balloons or in mesh-type devices, such as blood filters.

Local annealing is also especially useful in orthopedic implants, where the implant as a whole may be required to carry significant strains without deforming, while some small part of the implant, for example a locking element of the implant, may require some plasticity and/or may require to serve as a point that responds first to strain.

Figs. 6A and 6B illustrate a dental implant 100 in accordance with a preferred embodiment of the invention. Implant 100 comprises an inflatable body 110 with a wire 120 spiraling around it or attached to body 110 in any other pattern. In a preferred embodiment of the invention, an area, such as area 122 of wire 120 or the complete wire 120, is annealed, to prevent cracking of the wire when the implant is inflated. Alternatively or additionally, the annealing assists in a conformance between wire 120 and the bone or tooth material with which the implant is in contact.

Figs. 7A and 7B illustrate hip screws, in accordance with preferred embodiments of the invention. Fig. 7A illustrates a compressive hip screw 132 that has a head 134 embedded in a first hip part 130 and has a shaft 138 screwed into a base 140 in a second hip part 131. Thus, the hip is held together by compression between the two ends of screw 132. In a preferred embodiment of the invention, head 134 is an expandable head which is expanded after head 134 is sufficiently inserted into hip part 130. Preferably, one or more durable bars 136 (or other protrusions) are located on the circumference of head 134, for example in a manner similar to the structure of screw 10. Bars 136 preferably hold head 134 in place and prevent screw 132 from moving within the hip. In some cases, bar 136 is used to stiffen head 134 and/or to compress spongy bone, when head 134 is inserted into hip part 130. In other cases, bar 136 and/or the other protrusions are provided and/or machined to encourage bone ingrowth.

Alternatively or additionally to having a bar 136 on head 134, non-rib protrusion patterns, such as a grid, are placed on head 134. Such non-rib protrusions are advantageous for hip screw 132, as head 134 is not substantially required to oppose bending strains as is required from intramedullar nails.

Fig. 7B illustrates a dynamic hip screw 150, comprising a head 154 and a shaft 156. In dynamic screw 150, shaft 156 is not rigidly fixed to a base 152. Instead, shaft 156 is restrained

to move along the axis of base 152. Preferably, head 154 comprises an expanding head with a spiral shaped protrusion bar 158. Alternatively, head 134 with bars 136 and/or any other expanding head may be used in screw 150.

In some embodiments, the head is inflated using a fluid, such as silicon gel which is stored in the shaft and advanced into the head by rotating a screw in the shaft, thereby reducing the free volume in the shaft.

In some preferred embodiments of the present invention, heads 134 and/or 154 are partially or entirely annealed to allow inflation of the heads without breakage. In a preferred embodiment of the present invention, parts of bars 136 and/or 158 are also partially or entirely annealed, for example at their point of maximum expansion. Screws similar to screws 132 and 150 or at least utilizing similar heads, may also be used in other parts of the body in place of other implants such as regular prior art screws.

In weak bones, especially osteoporosic bones, such as common in older patients, expandable heads are generally expected to yield better holding power than threaded screws. Also, by periodically increasing the inflation, a loose screw can be tightened. It is noted, however, that in some cases it may be advantageous to allow the grip of head 134 to weaken within hip part 130, after a while. In such cases bar 136 and/or 158 are annealed accordingly to allow timely retraction of screw 132 or 150.

Another example of an inflatable implant is a hip implant, where a portion that engages the femur can be an inflating shaft, similar in design to the nail described in Fig. 1A or the heads described in Figs. 7A and 7B.

The present invention has been described using non-limiting detailed descriptions of preferred embodiments thereof that are provided by way of example and are not intended to limit the scope of the invention. Variations of embodiments described will readily occur to persons of the art. In particular, not all the features in each embodiment are required and features may be combined between described embodiments. Furthermore, the terms "comprise," "include," "have" and their conjugates, shall mean, when used in the claims, "including but not necessarily limited to." The scope of the invention is limited only by the following claims:

CLAIMS

1. A method of metal processing of an orthopedic implant, comprising:
providing an orthopedic device having at least one expandable portion and at least one non-expandable portion; and
selectively annealing at least part of said expandable portion, using an energy beam.

2. A method according to claim 1, comprising not significantly annealing said non-expandable portion.

3. A method according to claim 1, wherein said non-expandable portion is elongated by said expandable portion.

4. A method according to claim 1 or claim 3, comprising significantly annealing at least a part of said non-expandable portion.

5. A method according to any of claims 1-4, comprising selectively annealing only part of said expandable portion.

6. A method according to claim 5, wherein said selective annealing maintains a boundary, non-annealed area between the expandable portion and the non-expandable portion.

7. A method according to claim 1, comprising cold-working said implant prior to said selective annealing.

8. A method according to claim 1, wherein said expandable and non-expandable portions comprise elongate sections of said implant.

9. A method according to any of claims 1-8, wherein said implant comprises an intramedullary nail.

10. A method according to any of claims 1-8, wherein said implant comprises an orthopedic implant.

11. A method according to any of claims 1-8, wherein said implant is a dental implant.

12. A method according to any of claims 1-8, wherein said implant is a hip screw.

13. A method according to any of claims 1-8, wherein said implant is a hip implant.

14. A method according to any of claims 1-8, wherein said implant is a mesh-type implant.

15. A method according to any of claims 1-14, wherein said non-expandable portion comprises a thick portion of said implant and wherein said expandable portion comprises a thin portion of said implant.

16. A method according to any of claims 1-15, wherein said beam comprises an electron beam.

17. A method according to any of claims 1-15, wherein said beam comprises a laser beam.

18. A method according to any of claims 1-15, wherein said beam comprises a plasma beam.

19. A method according to any of claims 1-18, wherein said selective annealing comprises annealing both by directly heating a part of the implant and by indirectly heating a second part of the implant using heat transported from the directly heated part of the implant.

20. A method according to any of claims 1-19, wherein said selective annealing comprises protecting at least a portion of said implant from annealing heat.

21. A method according to claim 20, wherein said protecting comprises providing a heat sink adjacent non-annealed portions.

22. A method according to claim 20, wherein said protecting comprises actively cooling non-annealed portions.

23. A method according to any of claims 1-22, comprising monitoring a temperature of at least a part of said implant using a sensor.

24. A method according to claim 23, wherein said monitored part comprises an annealed part.

25. A method according to claim 23, wherein said monitored part comprises a part not to be annealed.

26. A method according to claim 23, wherein monitoring the temperature comprises monitoring the temperature such that the annealed parts do not melt.

27. A method according to claim 23, wherein monitoring the temperature comprises monitoring the temperature to be above a level sufficient for annealing.

28. A method according to claim 23, wherein selectively annealing comprises controlling an intensity of heating, responsive to said sensor output.

29. A method according to claim 28, wherein said controlling comprises closed loop controlling.

30. A method according to claim 28, wherein said controlling comprises open loop controlling.

31. A method according to claim 28, wherein said controlling comprises modifying a characteristic of said energy beam in real-time.

32. A method according to claim 28, wherein said controlling comprises modifying a characteristic of said energy beam in a later run, responsive to measurements in a previous annealing run.

33. A method according to any of claims 1-32, wherein said selective annealing comprises

repeating heating a same location several times, until a desired annealing effect is achieved.

34. A method according to any of claims 1-33, wherein said annealing comprises annealing an entire thickness of said expandable portion.

35. A method according to any of claims 1-34, wherein said annealing increases the elongation of said annealed parts to at least 30%.

36. A method according to any of claims 1-34, wherein said annealing increases the elongation of said annealed parts to at least 40%.

37. A method according to any of claims 1-34, wherein said annealing increases the elongation of said annealed parts to at least 50%.

38. A method according to any of claims 1-34, wherein said annealing increases the elongation of said annealed parts to at least 60%.

39. A method according to any of claims 1-38, wherein said annealing increases the elongation of said annealed parts from about 12%.

40. An intramedullary nail, comprising:
a plurality of elongate cold-worked portions; and
a plurality of elongate annealed portions.

41. A nail according to claim 40, wherein said cold-worked portions are separated from said annealed portions by a at least one boundary portion.

42. A nail according to claim 41, wherein said boundary portion comprises an expandable portion of said nail.

43. A nail according to any of claims 40-42, wherein said cold-worked portions are thick and non-expandable.

44. A nail according to any of claims 40-43, wherein said annealed portions are thin and expandable.

45. A nail according to any of claims 40-44, wherein said annealed portions are annealed to their entire thickness.

46. A nail according to any of claims 40-45, wherein said nail is formed of stainless steel.

47. A nail according to any of claims 40-45, wherein said nail is formed of titanium.

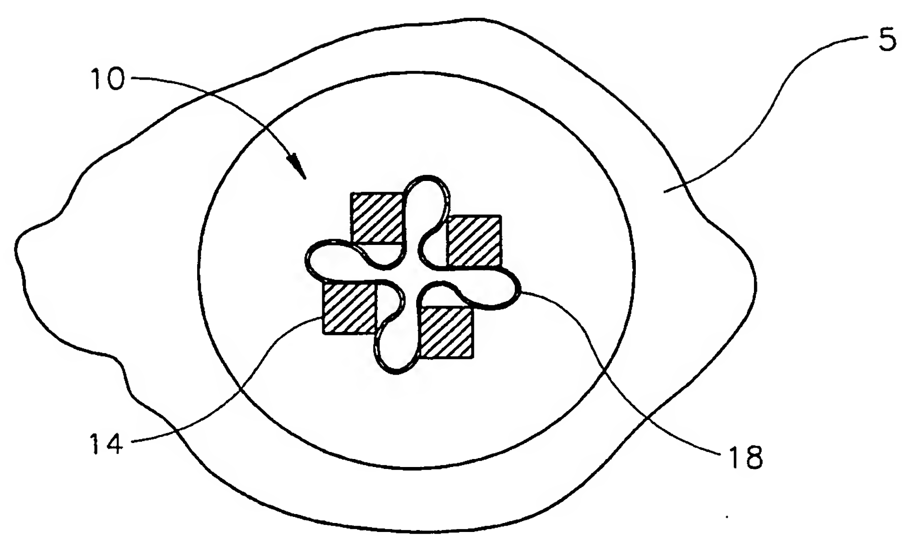

FIG.1A

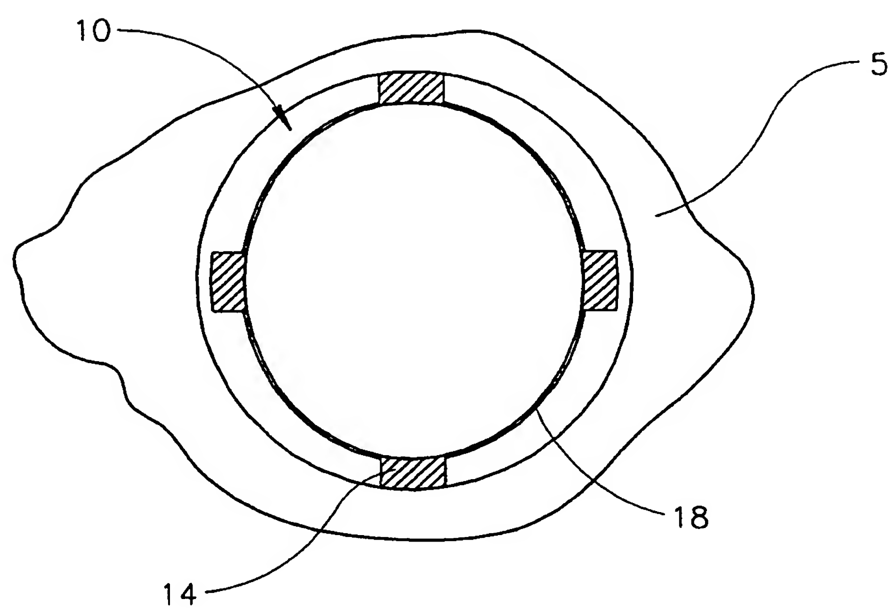

FIG.1B

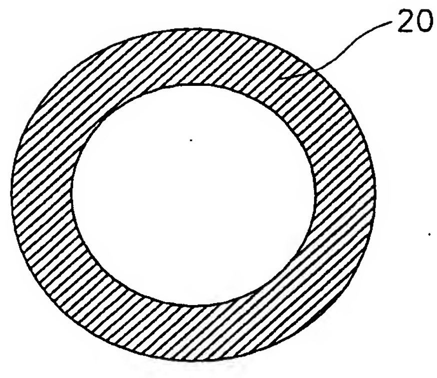

FIG.2

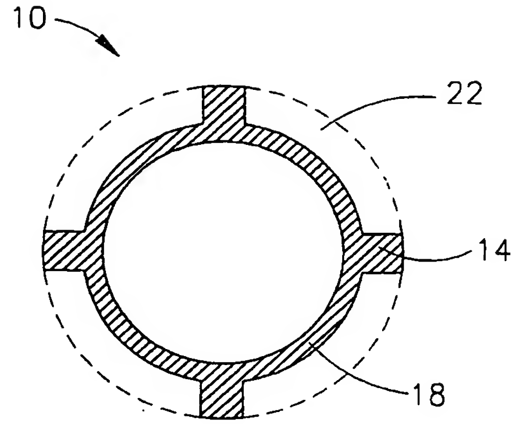

FIG.3

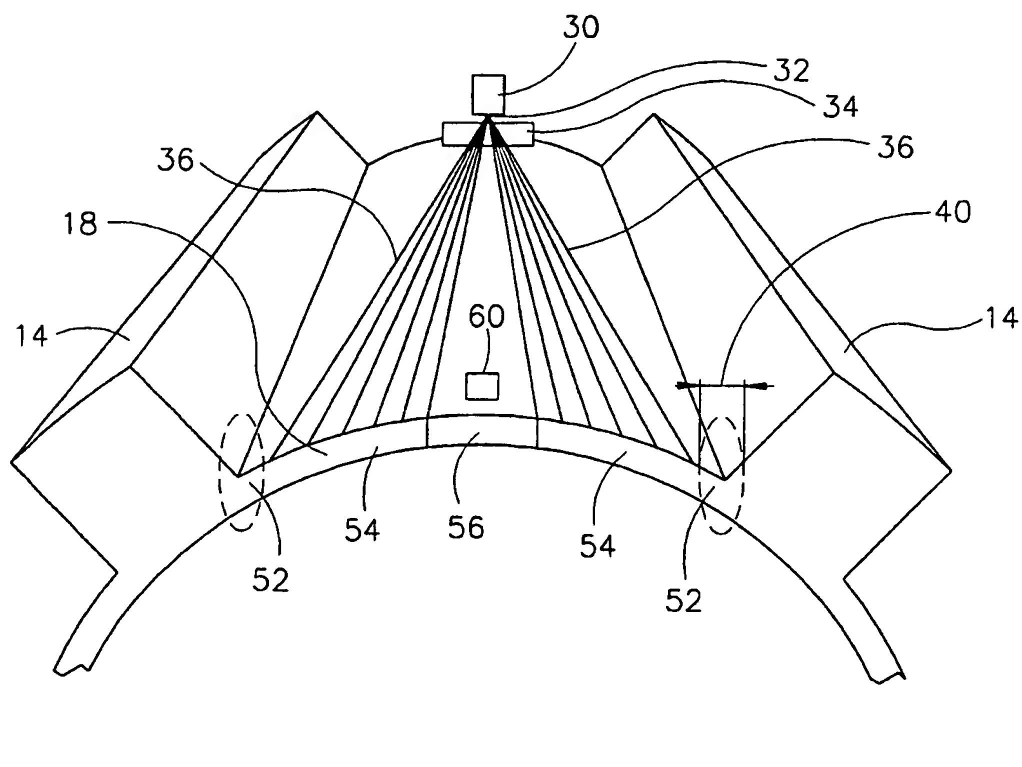

FIG.4

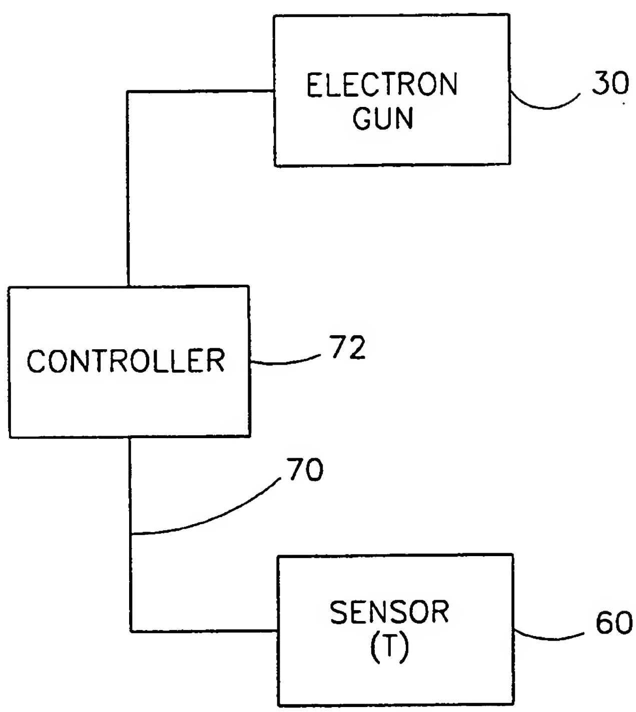

FIG.5

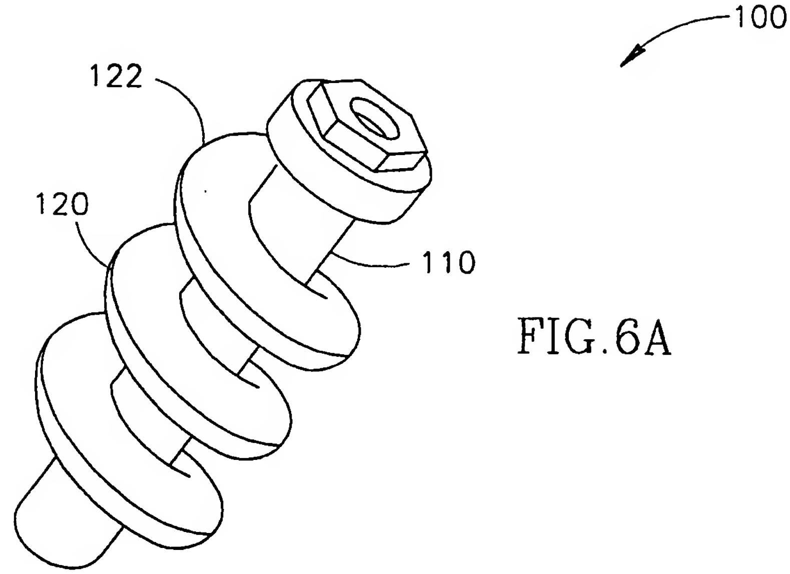

FIG.6A

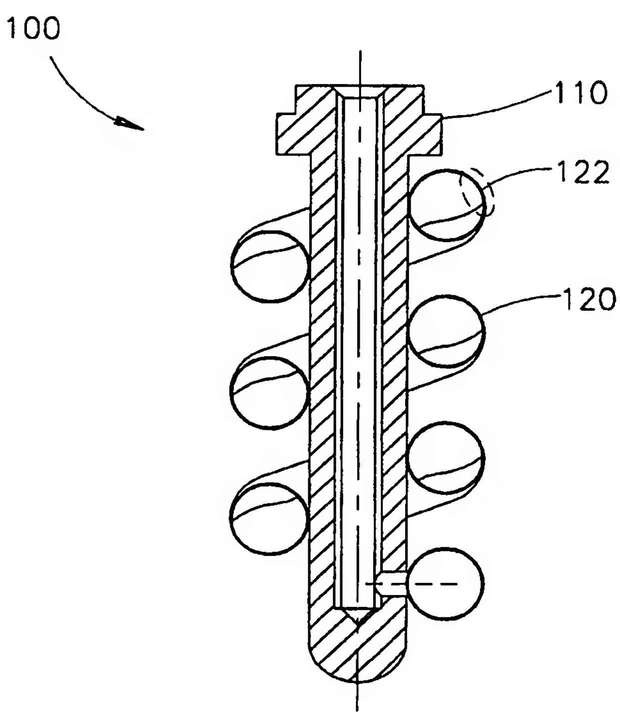

FIG.6B

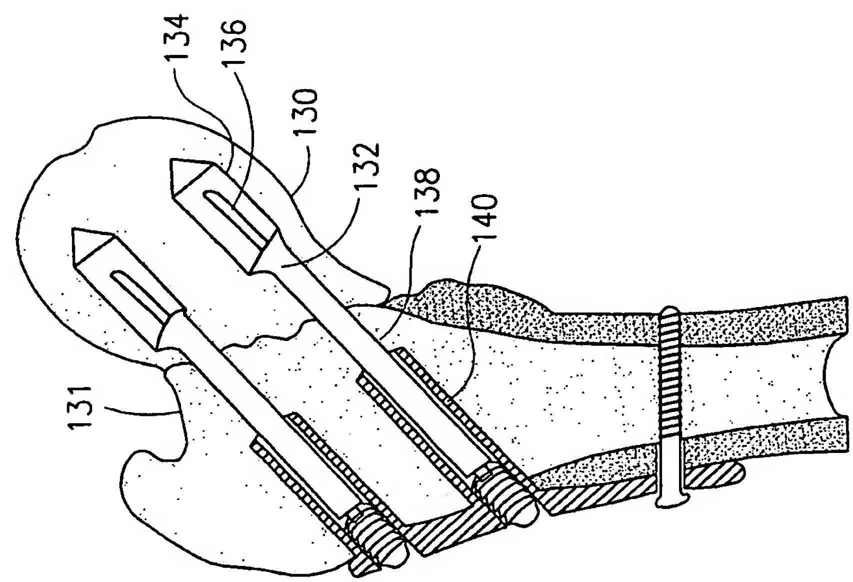

FIG.7A

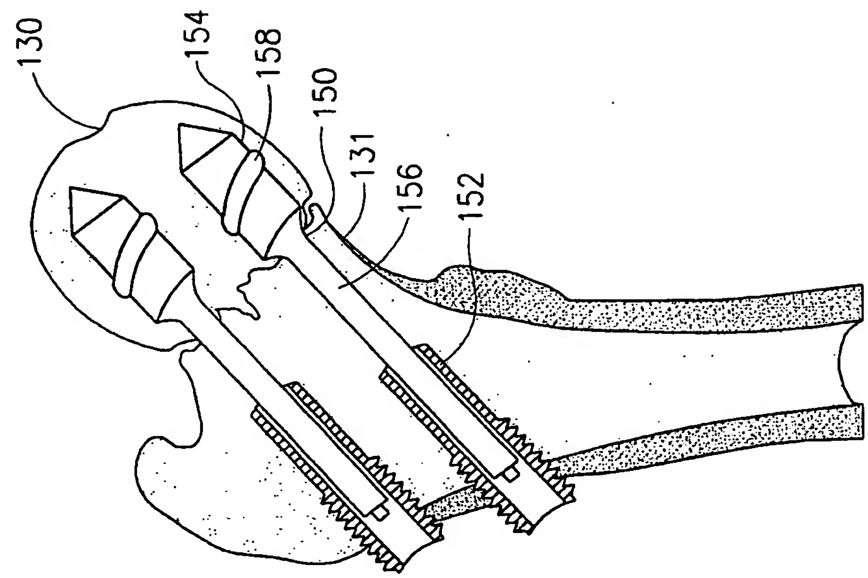

FIG.7B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 00/00055

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C21D9/26 C21D1/32 A61B17/72 A61B17/74 A61C8/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C21D A61B A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 38918 A (BEYAR MORDECHAY ;GLOBERMAN OREN (IL); MAGAL ELAD (IL)) 11 September 1998 (1998-09-11) page 51 -page 58; figures 20-22	1-47
A	US 5 012 066 A (MATSUTANI KANJI ET AL) 30 April 1991 (1991-04-30)	
A	FR 1 491 758 A (LEBOCEY & CIE) 27 November 1967 (1967-11-27)	
P,X	DE 299 04 852 U (SÄCHSISCHE ELEKTRONENSTRAHL GMBH) 27 May 1999 (1999-05-27) cited in the application the whole document	1,40

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 May 2000	08/06/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 00/00055

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9838918 A	11-09-1998	AU 6513698 A	22-09-1998
US 5012066 A	30-04-1991	JP 3090237 A	16-04-1991
FR 1491758 A	27-11-1967	NONE	
DE 29904852 U	27-05-1999	NONE	